REMARKS

In the Final Action dated July 3, 2003, claims 29-38 and 52-54 are pending and under consideration. Claim 53 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 29-38 and 52-54 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking an enabling disclosure. Claims 29-32, 34-38 and 52-54 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. (WO 95/25541). Claims 29-32, 34-38 and 52-54 are also rejected under 35 U.S.C. §102(e) as allegedly anticipated by Conrad et al. (U.S. Patent 5,889,166).

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance or at least in better condition for appeal. Favorable consideration of all pending claims is therefore respectfully requested.

Claim 53 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The claim recites that the homogenate is "a whole cell preparation of *Neospora*". The Examiner contends that it is unclear as to whether the claim is intended to encompass whole cells or disrupted whole cells.

Applicants respectfully submit that it is clear to those skilled in the art that the cells are disrupted to prepare a homogenate. In addition, at page 9 of the specification, the term "whole cell preparation" is defined as a homogenate that comprises all of the components produced by the homogenization or disruption. As such, it is respectfully submitted that claim 53 is not indefinite. Withdrawal of the rejection of claim 53 under 35 U.S.C. §112, second paragraph is therefore respectfully requested.

Claims 29-38 and 52-54 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enabling support.

The Examiner acknowledges that the specification is enabling for a method of protecting a mammal against neosporosis by administering to the mammal a vaccine comprising an immunologically effective amount of a *Neospora* homogenate as prepared in Example 1 of the specification, i.e., *Neospora* antigen (NSA) preparation. However, the Examiner alleges that the specification does not provide enablement for a method of vaccination by administration of a homogenate prepared from cells of *Neospora*, as presently claimed. The Examiner contends that claim 29 is so broad as to read on homogenizing cells containing tachyzoites, i.e., host cells containing *Neospora* cells are homogenized. In this connection, the Examiner states that the prior art teaches that it is extremely unpredictable to treat or prevent neosporosis in mammals. Citing Barr et al. (J. Vet Diagnosis. 6(2): 7308, 1993), Lindsay et al. (Am.J.Vet Res. 56(9): 1176-1180, 1995), and Lindsay et al. (J.Parasitol. 76(3): 410-413, 1990), the Examiner states that the prior art specifically teaches that homogenates prepared from cells of *Neospora* can be used to induce neosporosis in mammals. The Examiner contends that the vaccine, as recited in the instantly claimed methods, does not distinguish over the homogenates used in these prior art references, which actually induce, not protect against, neosporosis. The Examiner suggests that the claims be amended to incorporate the distinguishing characteristics of Applicants' homogenate.

In response, Applicants respectfully submit that the term "homogenate", as presently recited in the claimed methods, is defined in the specification at page 9, lines 12-13, as a preparation obtained by homogenizing or disrupting *Neospora* cells, i.e., by disrupting *Neospora* tachyzoites, bradyzoites, oocysts or a mixture thereof. It is abundantly clear to one skilled in the

art that a homogenate of *Neospora* in the context of the present invention is not a homogenate of host cells infected with *Neospora.* In contrast, the references cited by the Examiner, i.e., Barr et al. (1993), Lindsay et al. (1995) and Lindsay et al. (1990), merely disclose the preparation of live tachyzoites by disrupting infected host cells, and the use of these live tachyzoites for inducing neosporosis in a mammal. None of the cited references teach the preparation of a homogenate of *Neospora* and the use of a *Neospora* homogenate for inducing protective immunity in a mammal against neosporosis.

In an effort to favorably advance the prosecution of the present application, Applicants have amended independent claim 29 to further delineate the homogenate as comprising a whole cell preparation of *Neospora* tachyzoites, which is prepared by homogenizing or disrupting *Neospora* tachyzoites and is free of viable tachyzoites. Support for such amendment is found in previously presented claims 52-53 and in the specification, e.g., at page 9, lines 1-3, 7-8 and 13-14. Claims 52-53 have been canceled without prejudice in view of the amendment to claim 29. It is respectfully submitted that no new matter is introduced by the instant amendment.

Applicants respectfully submit that the claims, as presently amended, are fully supported by the specification in accordance with 35 U.S.C. § 112, first paragraph. The Examiner's attention is directed to pages 14-20 of the specification, wherein it is shown that a homogenate prepared from *Neospora* tachyzoites induced protective immunity in mammals. For example, see pages 16-20, Examples 2-3 of the present specification.

Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 29-32, 34-38 and 52-54 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. (WO 95/25541).

The Examiner alleges that Conrad et al. teach a homogenate prepared from a culture of biologically pure, isolated bovine *Neospora* tachyzoites. The Examiner contends that the *Neospora* preparation disclosed by Conrad et al. clearly meets Applicants' definition of a homogenate. Furthermore, the Examiner alleges that Conrad et al. teach the use of the homogenate prepared therein for prevention of neosporosis. Specifically, the Examiner refers to page 23, lines 20-21, where Conrad states that a vaccine may comprise a crude extract of *Neospora* tachyzoites, bradyzoites or other stages, or comprise partially or completely purified *Neospora* protein preparations. Referring to page 33, lines 23-30 of Conrad et al., the Examiner also alleges that the homogenate prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from tachyzoites of the NC-1 strain. Therefore, the Examiner concludes that Conrad et al. anticipates the claimed methods of protecting a mammal against neosporosis by using a homogenate of *Neospora.*

Applicants respectfully submit that Conrad et al. do not teach a homogenate of *Neospora* tachyzoites, as defined in the present specification and as recited in the present claims. In particular, the present claims characterize the homogenate as comprising "a whole cell preparation of *Neospora* tachyzoites, which is prepared by homogenizing or disrupting *Neospora* tachyzoites and is free of viable tachyzoites." The disclosure of Conrad et al. at page 4, lines 1-13; page 8, lines 5-15; page 33, lines 23-30; page 38, line 34; page 39, lines 5 and 15-30, which has been relied upon by the Examiner in raising the rejection, relates to the preparation of live, viable tachyzoites of *Neospora,* <u>not</u> a homogenate of tachyzoites obtained by homogenizing or

disrupting *Neospora* tachyzoites, as presently claimed.

As to the disclosure by Conrad et al. as it relates to the use of a crude extract of *Neospora* tachyzoites, bradyzoites or other stages for preparation of a vaccine, Conrad et al. provide no teaching as to how "a crude extract" is prepared. There is no indication in Conrad et al. as to whether such crude extract is a whole cell preparation of homogenized or disrupted *Neospora* tachyzoites, or whether the crude extract is free of viable *Neospora* tachyzoites, as presently claimed. As to page 33, lines 23-30 of Conrad et al., this portion of the reference merely comments on the reactivity of *in vitro* cultivated tachyzoites, i.e., live *Neospora* isolates, with rabbit polyclonal antisera. There is no teaching of a homogenate prepared from *Neospora* isolates or the antigenic components of such homogenate. Thus, the Examiner's conclusion that the homogenate prepared from a crude extract of isolated *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from NC- 1 tachyzoites, is unfounded. In fact, the term "extract", as understood by one skilled in the art, would mean a portion or fraction of all the components of *Neospora* tachyzoites, contrary to a "whole cell preparation" as recited in the present claims and defined in the present specification at page 9, lines 13-15. Applicants submit that a rejection of a claim under 35 U.S.C. §102(b) requires that the single prior art reference disclose every element of the claim. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v Crucible Inc., 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986).

Moreover, Applicants respectfully submit that Conrad et al. used live, infectious *Neospora* tachyzoites to infect cattle, attempting to induce immunity in the infected cattle. Conrad et al. provide no teaching, much less an enabling teaching, of any preparation from *Neospora* tachyzoites that is free of viable *Neospora* tachyzoites and has the capacity of inducing

protective immunity in a mammal against neosporosis. For anticipation, a prior art must place the invention in possession of the public by providing an enabling disclosure of the claimed subject matter. Scripps Clinic & Research Foundation v. Genetech. Inc., 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); Amgen. Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), certi. denied, 112 5. Ct. 169 (1991). In contrast, the present specification provides detailed teaching as to how a homogenate can be prepared from *Neospora* tachyzoites, e.g., at page 14-15 (Example 1), and how such a homogenate induced protective immunity in mammals, e.g., at pages 16-20 (Examples 2-3).

Accordingly, Applicants respectfully submit that Conrad et al. do not teach the claimed methods. The rejection of claims 29-32, 34-38 and 52-54 under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 29-32, 34-38 and 52-54 are also rejected under 35 U.S.C. §102(e) as allegedly anticipated by Conrad et al. (U.S. Patent 5,889,166).

Specifically, the Examiner alleges that the '166 patent teaches pharmaceutical compositions for the treatment and prevention of *Neospora* infections. The Examiner also alleges that the '166 patent discloses that *Neospora* vaccines may comprise a crude extract of *Neospora* tachyzoites (column 12, lines 51-52). According to the Examiner, the homogenate, which was prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2, has equivalent antigenic components to the homogenate prepared from *Neospora caninum* NC-l tachyzoites. Additionally, the Examiner alleges that the '166 patent specifically discloses that "cows infected using culture-derived tachyzoites mount a protective immune

response and prevent transplacental infection of the fetus" (col. 11, lines 60-65 and col. 28, lines 1-4).

It is observed that the teachings of the '166 patent, which the Examiner has relied upon in raising the §102(e) rejection, are substantially the same as the teachings of Conrad et al. (WO 95/25541) which the Examiner has relied upon in raising the §102(b) rejection. Applicants respectfully submit that like Conrad et al., the '166 patent does not teach the presently claimed methods.

Applicants respectfully submit that the '166 patent does not teach a homogenate of *Neospora* tachyzoites, as recited in the present claims, i.e., a homogenate which comprises "a whole cell preparation of *Neospora* tachyzoites, which is prepared by homogenizing or disrupting *Neospora* tachyzoites and is free of viable tachyzoites." The disclosure of the '166 patent, which has been relied upon by the Examiner in raising the rejection, relates to the preparation of live, viable tachyzoites of *Neospora,* not a homogenate of tachyzoites obtained by homogenizing or disrupting *Neospora* tachyzoites, as presently claimed.

Furthermore, with respect to the "crude extract" mentioned in the '166 patent in mere passing, there is no indication in the '166 patent as to whether such crude extract is a whole cell preparation of homogenized or disrupted *Neospora* tachyzoites, or whether the crude extract is free of viable *Neospora* tachyzoites, as presently claimed. As stated above, the absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB, Id.

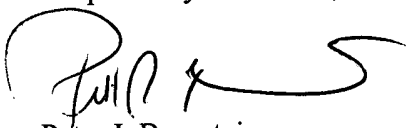
Moreover, Moreover, Applicants respectfully submit that Conrad et al. provide no teaching, much less an enabling teaching, of any preparation from *Neospora* tachyzoites that is free of viable *Neospora* tachyzoites and has the capacity of inducing protective immunity in a mammal against neosporosis. For anticipation, a prior art must place the invention in possession

of the public by providing an enabling disclosure of the claimed subject matter. See, Scripps, Id.; Amgen, Id.

Accordingly, Applicants respectfully submit that the '166 patent does not teach the claimed methods. The rejection of claims 29-32, 34-38 and 52-54 under 35 U.S.C. § 102(e) as allegedly anticipated by the '166 patent is overcome. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

XZ:ab